

*Applicant: Reiko M. Nakamura*  
*Serial No.: 09/877,802*  
*Supplemental Preliminary Amendment*

### REMARKS

The present application is directed to devices and compositions for detecting and diagnosing infectious diseases. In particular, the application relates to the use of a transdermal delivery device to diagnose infectious diseases such as mycobacterial infections. Support for claim amendments can be found generally throughout the specification. No new matter has been added. Following entry of the present amendment, Claims 34-57 will be pending.

#### *Interview*

On October 13, 2004, Dr. Carol Nacy (Sequella, Inc. CEO (assignee)), Dr. James Dean Johnson and Sima S. Kulkarni (applicant's representatives) met with Examiner Gabel and Examiner Le. During the meeting, the present application, together with possible strategies for overcoming the rejections, was discussed. Applicant's representatives agreed to submit an *In re Katz* declaration pursuant to 37 C.F.R. §1.132 (provided herewith); the Examiners suggested certain claim amendments and those amendments are entered herein.

#### *Rejection of Claims 21-23, 25-27 and 29 under 35 USC §102(a)*

In the September 3, 2003 Office Action the Examiner rejected Claims 21-23, 25-27 and 29 under 35 U.S.C. §102(a) as being unpatentable over Katsuhide *et al.* (JP 09206092, electronic translation version). Since the September 3, 2003 Office Action, Claims 21-23, 25-27 and 29 have been cancelled, however since corresponding claims are pending, the rejection is nevertheless addressed herein. Applicants respectfully traverse.

According to *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), a 35 U.S.C. 102(a) rejection based on a publication may be overcome by showing that it was published either by applicant himself/herself, or on his/her behalf. As stated in the Declaration provided herewith, Reiko Nakamura is an inventor for the cited Japanese patent application, and accordingly, pursuant to *In re Katz*, Katsuhide *et al.* should be removed as an anticipatory reference under 35 U.S.C. 102(a). (Currently, a facsimile version of Dr. Nakamura's Declaration is being provided; the Declaration bearing the original signature will be submitted via mail.)

In light of Dr. Nakamura's Declaration, the rejection of the claims under 35 U.S.C. §102(a) is rendered moot. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

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***Rejection of Claim 24 under 35 USC §103(a)***

In the September 3, 2003 Office Action, the Examiner stated that Claim 24 is rejected under 35 U.S.C. §103(a) as being unpatentable over Katsuhide *et al.* (JP 09206092, electronic translation version) in view of (1) Haga *et al.* (Tubercle and Lung Disease, June 1994, Supp. No. 1 (196), hereinafter "Haga-I" or (2) Haga *et al.* (Jpn. J. Med. Sci., Biol, 1996), hereinafter "Haga-II" . Since the September 3, 2003 Office Action, Claim 24 has been cancelled, however since corresponding claims are pending, the rejection is nevertheless addressed herein.

As discussed above, in light of Dr. Nakamura's Declaration, the rejection of the claims in light of Katsuhide *et al.* is rendered moot. In the absence of the primary reference (Katsuhide *et al.*) the secondary references (Haga-I and Haga-II) fail to obviate the invention. Applicant therefore respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

***Rejection of Claims 28 and 30 under 35 USC §103(a)***

Claims 28 and 30 under 35 USC §103(a) as being unpatentable over Katsuhide *et al.* in view of Barchfield *et al.* (U.S. 5,709,879). Since the September 3, 2003 Office Action, Claims 28 and 30 have been cancelled, however since corresponding claims are pending, the rejection is nevertheless addressed herein.

As discussed above, in light of Dr. Nakamura's Declaration, the rejection of the claims in light of Katsuhide *et al.* is rendered moot. In the absence of the primary reference (Katsuhide *et al.*) the secondary reference (Barchfield *et al.*) fails to obviate the invention. Applicant therefore respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

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**Conclusion**

In conclusion, Applicant believes that the claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. If the Examiner believes any informalities remain in the application, which may be corrected by Examiner's Amendment, whether any other issues can be resolved by telephone interview, telephone call with the undersigned attorney at (404) 745-2463 is courteously solicited.

Respectfully submitted,

  
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